REMARKS

Applicant respectfully requests reconsideration. Claims 1-6 and 8-11 were previously pending in this application. Claim 1 has been amended to remove the recitation of a non-elected invention in section (e) of the claim. Claim 1 has also been amended to clarify that after cleavage at a cleavable site in the composition, the amyloidogenic (poly)peptide retains its ability to self assemble. Support for the amendment can be found at least at page 4, line 38 through page 5, line 1 and in claim 6 as originally filed. Claims 8-11 have been amended to remove the multiple dependencies. Claims 6, 7, and 12-19 have been cancelled without prejudice. As a result, claims 1-5 and 8-11 are pending for examination with claim 1 being an independent claim. No new matter has been added.

Response to Amendment

Non-Elected Claims 7 and 12-19

Examiner indicated that that the reply to the final rejection mailed February 18, 2004 must have included cancellation of non-elected claims 7 and 12-19, and that appropriate action is required. Accordingly, Applicant has cancelled non-elected claims 7, and 12-19 without prejudice.

Claim 1

Claim 1 stands objected to for reciting a non-elected invention. The Examiner specifically cites section (e) of claim 1, and requires appropriate action in this regard. Applicant has amended claim 1 to remove section (e), which recited a non-elected invention. Applicant believes this amendment obviates the basis for the Examiner's objection to claim 1.

Claims 6 and 8-11

The Examiner indicated that claims 6 and 8-11 stand objected to and have not been further treated on the merits as being in improper form because a multiple dependent claim shall not serve as a basis for any other multiple dependent claim. Applicant submits that claims 6 and 8-11 were amended to remove the multiple dependencies in the response mailed November 18, 2002. Upon review of the file, it appears that the amendment that was filed for the removal of the multiple dependent status of the claims was not entered by the Office as it was filed in conjunction with a response considered to be non-compliant to the restriction requirement. Therefore, Applicant has amended herewith claims 8-11 to remove the multiple dependencies. Applicant has cancelled claim 6 with the amendment of claim 1 to include the limitation previously found in claim 6. Applicant respectfully submits that the current amendments obviate the objection to claims 8-11 and requests examination of these claims on the merits.

Rejections under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1-5 under 35 U.S.C. §112, first paragraph, as lacking adequate written description. Applicant has amended claim 1 to remove the term "functional derivative" of the fusion protein. Applicant believes this amendment obviates the Examiner's rejection of claim 1 under 35 U.S.C. §112, first paragraph. The Examiner also asserts that there

is a lack of adequate written description for the term: "fragment or derivative" of huntingtin protein in claim 5. Applicant respectfully traverses the rejection.

The basic requirement of the written description requirement is that the claimed invention must be described clearly enough to allow one of ordinary skill in the art to recognize that the inventors invented the claimed invention. *Vas-Cath v. Mahurkar* 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991); *Lockwood v. American Airlines, Inc.* 107 F.3d 1565, 41 USPQ2d 1961 (Fed. Cir. 1997); *In re Gosteli* 872 F.2d 1008, 10 USPQ 2d 1614 (Fed. Cir. 1989).

The Examiner states at page 4 of the Office Action that "the specification must provide sufficient distinguishing identifying characteristics of the genus". The Examiner indicates that the factors to be considered include "disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof". Applicant respectfully submits that identifying characteristics of the genus of fragments and derivatives of huntingtin protein for use in the invention as claimed are adequately described in the specification as filed, and that in light of the factors set forth by the Examiner and that one of ordinary skill would recognize from the specification as filed that Applicant was in possession of the invention at the time of filing.

The specification as filed includes numerous examples of fragments and derivatives of huntingtin polypeptides set forth in claim 5 that can be used in the composition of claim 1. For example, a number of GST fusion proteins are described in the Examples section and figures as filed. Described GST fusion proteins include huntingtin exon 1 and each includes a different number of glutamine repeats, which are encoded by CAG repeats. The Examples section describes how the fusion proteins can be made (see Examples 1-3) and the specification as filed provides a description of at least fusion proteins with 20, 30, 35, 51, 83, and 122 glutamine repeats.

The specification provides the nucleic acid sequences that encode a number of huntingtin polypeptide fragments as well as the amino acid sequences of the fragments. In addition to the sequence structure, the specification also describes functional characteristics of the polypeptides (e.g. the ability to form amyloid-like fibrils, and the ability to self-assemble) and describes structure/function associations between the length of the glutamine repeats and the tendency to self-assemble and form amyloid-like fibrils. For example, Example 3, at the last two lines of page 27, indicate that following digestion with trypsin, "in strong contrast to GST-HD51, the

GST-HD20 and GST-HD30 proteins did not show any tendency to form ordered high molecular weight structures". Thus, the specification not only provides numerous examples of fragments and derivatives of huntingtin polypeptides, but it also provides sequence structure, physical properties, functional characteristics, and a structure/function correlation of the polypeptides at issue.

Applicant submits that the presence of numerous examples of huntingtin polypeptide fragments that can be used in the claimed compositions along with clear delineation of the characteristics of the genus of useful huntingtin polypeptides would allow one of ordinary skill in the art to recognize that the inventor was in possession of the invention at the time of filing. Applicant respectfully submits that the specification as filed adequately meets the written description requirement mandating that the claimed invention be described clearly enough to allow one of ordinary skill in the art to recognize that the inventors invented the claimed invention.

Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1-5 under 35 U.S.C. §112, first paragraph, as lacking adequate written description.

Rejections under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 1-5 under 35 U.S.C. 112, second paragraph, as being indefinite. To address the Examiner's rejection, Applicant has amended claim 1 to remove the phrase "a functional derivative thereof". Applicant believes the amendment to claim 1 obviates the basis for the rejection of claims 1-5 under 35 U.S.C. 112, second paragraph, as indefinite.

Applicant, respectfully requests the rejection of claims 1-5 under 35 U.S.C. §112, second paragraph be withdrawn.

Rejections Under 35 U.S.C. §102(a)

The Examiner rejected claims 1-5 under 35 U.S.C. §102(a) as being anticipated by Onodera et al. (FEBS Letters, 1996, 399, pp.135-9).

The Examiner indicated in rejection of claims 1-5 under 35 U.S.C. §102(a) as anticipated by Onodera et al. in paragraph 12 of the Office Action mailed July 29, 2003 that "a fragment of huntingtin recited in claim 5 encompasses a fragment with as little as one amino acid". Applicant respectfully disagrees with this conclusion. As set forth in claim 1, from which claim

5 depends, the amyloidogenic (poly)peptide has the ability to self-assemble into amyloid-like fibrils or protein aggregates. The specification indicates at least at page 6 final paragraph that a certain number of polyglutamine repeats is necessary for the formation of amyloid-like fibrils *in vitro*, with a threshold value of between 35 and 48 glutamines. Thus, it would be apparent to one of ordinary skill that a fragment of huntingtin recited in claim 5 would not encompass fragment with a single amino acid.

Additionally, Applicant has amended claim 1 to include the limitation from former claim 6 indicating that the amyloidogenic (poly)peptide self-assembles subsequent to release from the fusion protein. The Onodera et al reference does not teach a fusion protein with this feature. Thus, the Onodera disclosure does not include every limitation of the claimed composition and does not anticipate the claimed invention.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-5 under 35 U.S.C. §102(a) as anticipated by Onodera et al.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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